

does not impose a directed plan of correction as an alternative sanction for a laboratory that has condition level deficiencies, it at least imposes a directed portion of a plan of correction when it imposes any of the following alternative sanctions:

- (1) State onsite monitoring.
- (2) Civil money penalty.
- (3) Suspension of all or part of Medicare payments.

(b) *Procedures*—(1) *Directed plan of correction*. When imposing this sanction, CMS—

(i) Gives the laboratory prior notice of the sanction and opportunity to respond in accordance with §493.1810;

(ii) Directs the laboratory to take specific corrective action within specific time frames in order to achieve compliance; and

(iii) May direct the laboratory to submit the names of laboratory clients for notification purposes, as specified in paragraph (b)(3) of this section.

(2) *Directed portion of a plan of correction*. CMS may decide to notify clients of a sanctioned laboratory, because of the seriousness of the noncompliance (e.g., the existence of immediate jeopardy) or for other reasons. When imposing this sanction, CMS takes the following steps—

(i) Directs the laboratory to submit to CMS, the State survey agency, or other CMS agent, within 10 calendar days after the notice of the alternative sanction, a list of names and addresses of all physicians, providers, suppliers, and other clients who have used some or all of the services of the laboratory since the last certification inspection or within any other timeframe specified by CMS.

(ii) Within 30 calendar days of receipt of the information, may send to each laboratory client, via the State survey agency, a notice containing the name and address of the laboratory, the nature of the laboratory's noncompliance, and the kind and effective date of the alternative sanction.

(iii) Sends to each laboratory client, via the State survey agency, notice of the rescission of an adverse action within 30 days of the rescission.

(3) *Notice of imposition of a principal sanction following the imposition of an alternative sanction*. If CMS imposes a

principal sanction following the imposition of an alternative sanction, and for which CMS has already obtained a list of laboratory clients, CMS may use that list to notify the clients of the imposition of the principal sanction.

(c) *Duration of a directed plan of correction*. If CMS imposes a directed plan of correction, and on revisit it is found that the laboratory has not corrected the deficiencies within 12 months from the last day of inspection, the following rules apply:

(1) CMS cancels the laboratory's approval for Medicare payment of its services, and notifies the laboratory of CMS's intent to suspend, limit, or revoke the laboratory's CLIA certificate.

(2) The directed plan of correction continues in effect until the day suspension, limitation, or revocation of the laboratory's CLIA certificate.

§493.1834 Civil money penalty.

(a) *Statutory basis*. Sections 1846 of the Act and 353(h)(2)(B) of the PHS Act authorize the Secretary to impose civil money penalties on laboratories. Section 1846(b)(3) of the Act specifically provides that incrementally more severe fines may be imposed for repeated or uncorrected deficiencies.

(b) *Scope*. This section sets forth the procedures that CMS follows to impose a civil money penalty in lieu of, or in addition to, suspending, limiting, or revoking the certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures of a laboratory that is found to have condition level deficiencies.

(c) *Basis for imposing a civil money penalty*. CMS may impose a civil money penalty against any laboratory determined to have condition level deficiencies regardless of whether those deficiencies pose immediate jeopardy.

(d) *Amount of penalty*—(1) *Factors considered*. In determining the amount of the penalty, CMS takes into account the following factors:

(i) The nature, scope, severity, and duration of the noncompliance.

(ii) Whether the same condition level deficiencies have been identified during three consecutive inspections.

(iii) The laboratory's overall compliance history including but not limited

to any period of noncompliance that occurred between certifications of compliance.

(iv) The laboratory's intent or reason for noncompliance.

(v) The accuracy and extent of laboratory records and their availability to CMS, the State survey agency, or other CMS agent.

(2) *Range of penalty amount.* (i) For a condition level deficiency that poses immediate jeopardy, the range is \$3,050–\$10,000 per day of noncompliance or per violation.

(ii) For a condition level deficiency that does not pose immediate jeopardy, the range is \$50–\$3,000 per day of noncompliance or per violation.

(3) *Decreased penalty amounts.* If the immediate jeopardy is removed, but the deficiency continues, CMS shifts the penalty amount to the lower range.

(4) *Increased penalty amounts.* CMS may, before the hearing, propose to increase the penalty amount for a laboratory that has deficiencies which, after imposition of a lower level penalty amount, become sufficiently serious to pose immediate jeopardy.

(e) *Procedures for imposition of civil money penalty—(1) Notice of intent.* (i) CMS sends the laboratory written notice, of CMS's intent to impose a civil money penalty.

(ii) The notice includes the following information:

(A) The statutory basis for the penalty.

(B) The proposed daily or per violation amount of the penalty.

(C) The factors (as described in paragraph (d)(1) of this section) that CMS considered.

(D) The opportunity for responding to the notice in accordance with § 493.1810(c).

(E) A specific statement regarding the laboratory's appeal rights.

(2) *Appeal rights.* (i) The laboratory has 60 days from the date of receipt of the notice of intent to impose a civil money penalty to request a hearing in accordance with § 493.1844(g).

(ii) If the laboratory requests a hearing, all other pertinent provisions of § 493.1844 apply.

(iii) If the laboratory does not request a hearing, CMS may reduce the proposed penalty amount by 35 percent.

(f) *Accrual and duration of penalty—(1) Accrual of penalty.* The civil money penalty begins accruing as follows:

(i) 5 days after notice of intent if there is immediate jeopardy.

(ii) 15 days after notice of intent if there is not immediate jeopardy.

(2) *Duration of penalty.* The civil money penalty continues to accrue until the earliest of the following occurs:

(i) The laboratory's compliance with condition level requirements is verified on the basis of the evidence presented by the laboratory in its credible allegation of compliance or at the time or revisit.

(ii) Based on credible evidence presented by the laboratory at the time of revisit, CMS determines that compliance was achieved before the revisit. (In this situation, the money penalty stops accruing as of the date of compliance.)

(iii) CMS suspends, limits, or revokes the laboratory's certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures.

(g) *Computation and notice of total penalty amount—(1) Computation.* CMS computes the total penalty amount after the laboratory's compliance is verified or CMS suspends, limits, or revokes the laboratory's CLIA certificate but in no event before—

(i) The 60 day period for requesting a hearing has expired without a request or the laboratory has explicitly waived its right to a hearing; or

(ii) Following a hearing requested by the laboratory, the ALJ issues a decision that upholds imposition of the penalty.

(2) *Notice of penalty amount and due date of penalty.* The notice includes the following information:

(i) Daily or per violation penalty amount.

(ii) Number of days or violations for which the penalty is imposed.

(iii) Total penalty amount.

(iv) Due date for payment of the penalty.

(h) *Due date for payment of penalty.* (1) Payment of a civil money penalty is due 15 days from the date of the notice specified in paragraph (g)(2) of this section.

(2) CMS may approve a plan for a laboratory to pay a civil money penalty, plus interest, over a period of up to one year from the original due date.

(i) *Collection and settlement*—(1) *Collection of penalty amounts.* (i) The determined penalty amount may be deducted from any sums then or later owing by the United States to the laboratory subject to the penalty.

(ii) Interest accrues on the unpaid balance of the penalty, beginning on the due date. Interest is computed at the rate specified in § 405.378(d) of this chapter.

(2) *Settlement.* CMS has authority to settle any case at any time before the ALJ issues a hearing decision.

[57 FR 7237, Feb. 28, 1992, as amended at 60 FR 20051, Apr. 24, 1995; 61 FR 63749, Dec. 2, 1996]

§ 493.1836 State onsite monitoring.

(a) *Application.* (1) CMS may require continuous or intermittent monitoring of a plan of correction by the State survey agency to ensure that the laboratory makes the improvements necessary to bring it into compliance with the condition level requirements. (The State monitor does not have management authority, that is, cannot hire or fire staff, obligate funds, or otherwise dictate how the laboratory operates. The monitor's responsibility is to oversee whether corrections are made.)

(2) The laboratory must pay the costs of onsite monitoring by the State survey agency.

(i) The costs are computed by multiplying the number of hours of onsite monitoring in the laboratory by the hourly rate negotiated by CMS and the State.

(ii) The hourly rate includes salary, fringe benefits, travel, and other direct and indirect costs approved by CMS.

(b) *Procedures.* Before imposing this sanction, CMS provides notice of sanction and opportunity to respond in accordance with § 493.1810.

(c) *Duration of sanction.* (1) If CMS imposes onsite monitoring, the sanction continues until CMS determines that the laboratory has the capability to ensure compliance with all condition level requirements.

(2) If the laboratory does not correct all deficiencies within 12 months, and a

revisit indicates that deficiencies remain, CMS cancels the laboratory's approval for Medicare payment for its services and notifies the laboratory of its intent to suspend, limit, or revoke the laboratory's certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures.

(3) If the laboratory still does not correct its deficiencies, the Medicare sanction continues until the suspension, limitation, or revocation of the laboratory's certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures is effective.

[57 FR 7237, Feb. 28, 1992, as amended at 60 FR 20051, Apr. 24, 1995]

§ 493.1838 Training and technical assistance for unsuccessful participation in proficiency testing.

If a laboratory's participation in proficiency testing is unsuccessful, CMS may require the laboratory to undertake training of its personnel, or to obtain necessary technical assistance, or both, in order to meet the requirements of the proficiency testing program. This requirement is separate from the principal and alternative sanctions set forth in §§ 493.1806 and 493.1807.

§ 493.1840 Suspension, limitation, or revocation of any type of CLIA certificate.

(a) *Adverse action based on actions of the laboratory's owner, operator or employees.* CMS may initiate adverse action to suspend, limit or revoke any CLIA certificate if CMS finds that a laboratory's owner or operator or one of its employees has—

(1) Been guilty of misrepresentation in obtaining a CLIA certificate;

(2) Performed, or represented the laboratory as entitled to perform, a laboratory examination or other procedure that is not within a category of laboratory examinations or other procedures authorized by its CLIA certificate;

(3) Failed to comply with the certificate requirements and performance standards;

(4) Failed to comply with reasonable requests by CMS for any information